K113483

PHILIPS

Philips Medical Systems (Cleveland) Inc.

510(k) Summary

SEP 26 2012

Philips Iterative Reconstruction Technique (IRT)[1] Software Application

The summary of this 510(k) provides safety and effectiveness information submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter:

   Philips Medical Systems (Cleveland), Inc.
   595 Miner Road
   Cleveland, OH 44143

   Contact:

   Christine Anderson
   Regulatory Affairs Specialist
   Tel.: (440) 483-7732
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   Date of Summary: November 21, 2011

2. Device Name and Classification

Device Name:	Philips IRT Software Application
Device Classification:	Computed Tomography X-Ray System. The FDA has classified the Computed Tomography X-Ray System and its accessories as Class II in 21 CFR 892.1750 (Product Code: 90 JAK)

3. Predicate Device Information

   The Philips IRT Software Application is comparable in type and substantial equivalence to the legally marketed devices currently in commercial distribution, namely:
   a. Philips Brilliance Volume CT System – K060937

4. Device Description

   The Philips IRT Software Application is a software option used for the reduction

[1] Iterative Reconstruction Technique (IRT) is the current working descriptive name for the reconstruction process. During development the term iMR, a preliminary engineering name, was also used. Documentation in this 510(k) may use either the term Iterative Reconstruction Technique (IRT) or iMR. Both terms refer to the same process.

of noise in an image. IRT iteratively reconstructs raw data from a Philips CT Scanner to produce images containing noise levels less than or equal to images produced by standard Filtered Back Projection (FBP) reconstruction. This feature will be used by radiologists as a supplementary method to reconstruct CT raw data, in addition to traditional FBP.

5. Indications for Use

The Philips IRT Software Application is intended to iteratively reconstruct raw data from a Philips CT Scanner to produce images containing noise levels less than or equal to images produced by standard Filtered Back Projection reconstruction. Resulting IRT images are to be used to supplement conventional Filtered Back Projection images to aid the physician in diagnosis; they are not to be used as the sole basis for diagnosis.

6. Comparison to Predicate

In the opinion of Philips IRT Software Application is of a comparable type and substantially equivalent to the Philips Brilliance Volume CT System, the legally marketed device described in paragraph 3 above. IRT uses similar operating principles for the reconstruction of raw data from a CT scanner into viewable images. Most of the image reconstruction steps are identical to the FBP reconstruction except that IRT contains an iterative step in the preprocessing chain that reduces the noise and during the image post processing chain where there is an additional function that reduces pixel-to-pixel noise in the images while keeping the structures intact.

Predicate	510(k) Number	Cleared
Brilliance Volume	K060937	June 5, 2006

7. Safety

The Philips IRT software application is manufactured in accordance with the Quality System Regulation (QSR) 21 CFR 820 and to International Standards ISO 13485:2003. Potential hazards are identified in a hazard analysis and controlled in the following manner:

Software: Safety is assured by the company procedures that conform to accepted practices, including the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

Instructions for Use are provided with the software application for the safe and effective operation of the application by the user.

8. Performance Testing Summary

Non-clinical testing was conducted with the IRT Software Application in the following manner:

Objective image quality testing was conducted using phantoms and following the methodology in IEC 61223-3-5, Evaluation and routine testing in medical departments – Parts 3-5: Acceptance test – Imaging performance of computed tomography x-ray equipment for determining noise, CT number, CT number uniformity and high contrast spatial resolution. Raw CT scan data using phantoms were reconstructed both with filtered backprojection and the IRT software application for comparison. Additionally, low contrast detectability (LCD) was evaluated via an observer study. In this study, a cohort of human subjects was required to identify a low contrast test object in a panel of four images. In order to characterize the statistical nature of the detection of a low contrast object in an image with noise, the test was repeated multiple times for each test subject, and multiple test subjects were used. The resulting data confirmed the improved LCD using the IRT application.

Clinical image raw data sets were reconstructed with filtered backprojection and then with the IRT software application to compare noise reduction. Resulting data confirmed that the IRT application provides equivalent or better noise reduction.

In summary, the verification test evidence indicates that, under the conditions evaluated, IRT affords a reduction in noise and an improvement in LCD, with no degradation in high contrast spatial resolution, CT number accuracy, or CT number uniformity. Therefore, the IRT application provides equivalent or better noise reduction as compared to the filtered backprojection used in the Brilliance Volume CT.

Based on the above considerations, it is Philips's opinion that the results of the verification and validation testing and the results of the risk analysis demonstrates safety and effectiveness of the Philips IRT Software Application and that it is substantially equivalent to the predicate device documented above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -- WO66-G609
Silver Spring, MD 20993-0002

SEP 26 2012

Ms. Christine Anderson
Regulatory Affairs Specialist
Philips Medical System (Cleveland) Inc.
595 Miner Road
CLEVELAND OH 44183

Re: K113483
Trade/Device Name: Philips Iterative Reconstruction Technique Software Application
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: August 22, 2012
Received: August 23, 2012

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

PHILIPS

Philips Medical Systems (Cleveland) Inc.

510(k) Number (if known): K K113483

Device Name: Philips Iterative Reconstruction Technique Software Application

Indications for Use:

The Philips Iterative Reconstruction Technique (IRT) Software Application is intended to reconstruct raw data from a Philips CT Scanner to produce images containing noise levels less than or equal to images produced by standard Filtered Back Projection reconstruction. Resulting (IRT) images are to be used to supplement conventional Filtered Back Projection images to aid the physician in diagnosis; they are not to be used as the sole basis for diagnosis.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (Part 21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER LINE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
ODE/D
510k K113483